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Docket No.: 2194-0042-23



COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

ATTORNEYS AT LAW

J. DEREK MASON
(703) 413-3000
DMASON@OBLON.COM

RE: Application Serial No.: 09/938,728
Applicants: GWYN CUTSFORTH, ET AL.
Filing Date: AUGUST 27, 2001
For: COAGULATION ASSAY REAGENTS CONTAINING
LANTHANIDES
Group Art Unit: 1651
Examiner: GITOMER, RALPH J.

SIR:

- Attached hereto for filing are the following papers:
- Petition under 37 C.F.R. §1.181, Copy of Date-stamped filing receipt dated August 27, 2001,
 - Copy of Information Disclosure Statement filed August 27, 2001,
 - Copy of PTO Form 1449 filed August 27, 2001 (3 pp.),
 - Copy of Date-stamped filing receipt dated August 7, 2003,
 - Copy of Information Disclosure Statement filed August 7, 2003,
 - Copy of PTO Form 1449 filed August 7, 2003 (1 pp.)

Our check in the amount of -0- is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

J. Derek Mason, Ph.D.

Registration No. 35,270

Customer Number
22850
(703) 413-3000 (phone)
(703) 413-2220 (fax)



DOCKET NO.: 2194-0042-23

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: :GROUP ART UNIT: 1651
INVENTOR: GWYN CUTSFORTH, ET AL. :EXAMINER: GITOMER, RALPH J.
SERIAL NO.: 09/938,728 :ALLOWED: OCTOBER 10, 2003
FILED: AUGUST 27, 2001 :
FOR: COAGULATION ASSAY
REAGENTS CONTAINING
LANTHANIDES

PETITION UNDER 37 C.F.R. §1.181

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Applicants respectfully request consideration of the references submitted by
Applicants under 37 C.F.R. §1.97, on August 27, 2001 and August 7, 2003.
On August 27, 2001 and August 7, 2003, Applicants submitted an Information
Disclosure Statement under 37 C.F.R. §1.97. As evidence thereof, Applicants submit
herewith copies of (2) date-stamped filing receipts, dated August 27, 2001 and
August 7, 2003, (2) Information Disclosure Statements, and (2) PTO Form 1449's. However,
the Examiner has failed to provide for the record an initialed and signed copy of the Form
1449.

Applicants respectfully request that the Office provide, for the record, an initialed and signed copy of Applicant's Form 1449's filed on August 27, 2001 and August 7, 2003.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

A handwritten signature in black ink, appearing to read "J. Derek Mason", with a long horizontal flourish extending to the right.

J. Derek Mason
Attorney of Record
Registration No.: 24,618

Telephone: (703) 413-3000
Facsimile (703) 413-2220



OSMM&N File No. 2194-0042-23

Dept.: CHEMICAL

By: JDM:ekd

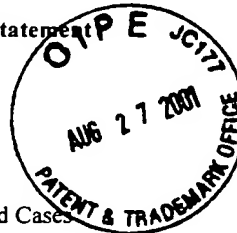
Serial No. NEW APPLICATION

In the matter of the Application of: Gwyn A. CUTSFORTH, et al.

For: COAGULATION ASSAY REAGENTS CONTAINING LANTHANIDES
AND A PROTEIN C ASSAY USING SUCH A LANTHANIDE-
CONTAINING REAGENT

The following has been received in the U.S. Patent Office on the date stamped hereon:

- ☒ 26 pp. Specification & 84 Claims/Drawings 9 Sheets
 - and 2 pages Application Data Sheet
 - ☐ Combined Declaration, Petition & Power of Attorney (pages,)
 - ☐ List of Inventor Names and Addresses
 - ☒ Utility Patent Application Transmittal ☐ CPA
 - ☐ Request for Priority ☐ Priority Doc
 - ☒ Check for \$2,632.00 ☒ Dep. Acct. Order Form
 - ☒ Fee Transmittal Form
 - ☐ Assignment/PTO 1595 pages:
 - ☐ Letter to Official Draftsman
 - ☐ Letter Requesting Approval of Drawing Changes
 - ☐ Drawings sheets ☐ Formal
 - ☐ PTO Cover Letter
 - ☐ Amendment
 - ☒ Information Disclosure Statement
 - ☒ Cited References (23)
 - ☐ Search Report
 - ☐ Statement of Relevancy
 - ☐ IDS/Related/List of Related Cases
 - ☐ Response to Restriction Requirement
 - ☐ Rule 132 Declaration
 - ☐ Request for Extension of Time under 37 C.F.R. §1.136 ()
 - ☐ Notice of Appeal
 - ☐ Appeal Brief
 - ☐ Reply Brief
 - ☐ Issue Fee Transmittal
 - ☒ White Advance Serial Number Card
 - ☐
- Due Date: August 27, 2001



☒ PTO-1449

☐ Cited Pending Applications ()

☐ Election Response

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Gwyn A. CUTSFORTH, et al.
SERIAL NO: NEW APPLICATION
FILED: HEREWITH
FOR: COAGULATION ASSAY REAGENTS CONTAINING LANTHANIDES AND A PROTEIN C ASSAY USING SUCH A LANTHANIDE-CONTAINING REAGENT

INFORMATION DISCLOSURE/RELATED CASE STATEMENT UNDER 37 CFR 1.97

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The applicants wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- ☐ Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- ☐ A check is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



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(OSMMN 10/98)

J. Derek Mason, Ph.D.

Attorney of Record

Registration No. 35,270

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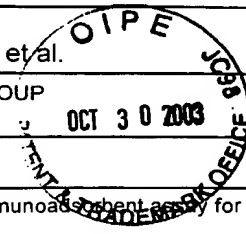
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Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 2194-0042-23		SERIAL NO. NEW APPLICATION	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Gwyn A. CUTSFORTH, et al.		GROUP	
				FILING DATE HEREWITH			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO		
	AO						
	AP						
	AQ						
	AR						
	AS						
	AT						
	AU						
	AV						
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AW	A. BROEKMANS, et al., "Congenital Protein C Deficiency and Venous Thromboembolism, A Study of Three Dutch Families", THE NEW ENGLAND JOURNAL OF MEDICINE, Vol. 309, No. 6, pp. 340-344, 1983.					
	AX	J. GRIFFIN, et al., "Protein C, an Antithrombotic Protein, Is Reduced in Hospitalized Patients with Intravascular Coagulation", BLOOD, Vol. 60, No. 1 (July), pp. 261-264, 1982.					
	AY	R. MARLAR, et al., "Serial Studies of Protein C and Its Plasma Inhibitor in Patients with Disseminated Intravascular Coagulation", BLOOD, Vol. 66, No. 1 (July), pp. 59-63, 1985.					
	AZ	"Protein C in the Treatment of coagulopathy in meningococcal disease", THE LANCET, Vol. 347, page 1767, June 1996.					
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 2194-0042-23		SERIAL NO. NEW APPLICATION	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Gwyn A. CUTSFORTH, et al.			
				FILING DATE HEREWITH		GROUP	
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AAA	O. P. SMITH, et al., "Use of protein-C concentrate, heparin, and haemodiafiltration in meningococcus-induced purpura fulminans", THE LANCET, Vol. 350, pp. 1590-1593, November 1997.					
	AAB	R. FAVIER, et al., "Simultaneous administration of antithrombin III and protein C concentrates for the treatment of a devastating coagulopathy in a child", HEMATOL. CELL THER., Vol. 40, pp. 67-70, 1998.					
	AAC	J. PARKINSON, et al., "Stable Expression of a Secretable Deletion Mutant of Recombinant Human Thrombomodulin in Mammalian Cells", THE JOURNAL OF BIOLOGICAL CHEMISTRY, Vol. 265, No. 21, pp. 12602-12610, July 1990.					
	AAD	B. GERLITZ, et al., "Identification of the predominant glycosaminoglycan-attachment site in soluble recombinant human thrombomodulin: potential regulation of functionality by glycosyltransferase competition for serine ⁴⁷⁴ ", BIOCHEM J., Vol. 295, pp. 131-140, 1993.					
	AAE	D. T. BERG, et al., "High-Level Expression of Secreted Protein s form Cells Adapted to Serum-Free Suspension Culture", BIOTECHNIQUES, Vol. 14, No. 6, pp. 972-978, 1993.					
	AAF	J. PARKINSON, et al., "STRUCTURE-FUNCTION STUDIES OF THE EPIDERMAL GROWTH FACTOR DOMAINS OF HUMAN THROMBOMODULIN", BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, Vol. 185, No. 2, pp. 567-576, 1992.					
	AAG	C. E. WHITE, et al., "Large-scale expression, purification and characterization of small fragments of thrombomodulin: the roles of the sixth domain and of methionine 388", PROTEIN ENGINEERING, Vol. 8, No. 11, pp. 1177-1187, 1995.					
	AAH	D. E. JACKSON, et al., "Purification and characterization of two forms of soluble thrombomodulin from human urine", EUR. J. BIOCHEM., Vol. 221, pp. 1079-1087, 1994.					
	AAI	S. M. RICHARDS, et al., "Quantitative and Functional Assays compared for Determination of Zymogen and Activated Human Protein C", CLIN. CHEM. Vol. 36, No. 11, pp. 1892-1896, 1990.					
	AAJ	L. BAJZAR, et al. "Both Cellular And Soluble Forms of Thrombomodulin Inhibit Fibrinolysis by Potentiating The Activation of Thrombin-activable Fibrinolysis Inhibitor", J. BIOL. CHEM., Vol. 273, No. 5, 1998. ABSTRACT ONLY					
	AAK	M. F. HOCKIN, et al., "Inactivation on human umbilical vein endothelial cells", ARTERIOSCLER., THROMB., VASC. BIOL., Vol. 17, No. 11, 1997. ABSTRACT ONLY					
	AAL	A. J. GALE, et al., "Nonenzymic anticoagulant activity of the mutant seine protease Ser360Ala-activated protein C mediated by factor Va", PROTEIN SCIENCE, Vol. 6, No. 1, 1997. ABSTRACT ONLY					
	AAM	S. YU, et al., "Construction, Expression, and Properties of a Recombinant chimeric Human Protein C with Replacement of Its Growth Factor-like Domains by those of Human Coagulation Factor IX", BIOCHEMISTRY, Vol. 33, No. 3, 1994. ABSTRACT ONLY					
	AAN	C. L. ORTHNER, et al., "A sensitive and facile assay for the measurement of activated protein C activity levels in vivo", THROMB. HAEMOSTASIS, Vol. 69, No. 5, 1993. ABSTRACT ONLY					
	AAO	K. G. MANN, et al., "Active site-specific immunoassays", BLOOD, Vol. 76, No. 4, 1990. ABSTRACT ONLY					
	AAP	K. F. STOCKER, et al., "Snake protein C activator, methods of preparation and use thereof", US Patent. ABSTRACT ONLY					
	AAQ	S. NAKAMURA, et al., "Assay methods for protein C (and protein S)", RINSHO BYORI, RINJI ZOKAN, Vol. 70, 1987, ABSTRACT ONLY					
Examiner				Date Considered			
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Gwyn A. CUTSFORTH, et al.			
				FILING DATE HEREWITH			
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	BBA	G. A. SOFF, et al., "Protein C levels in nephrotic syndrome: use of a new enzyme-linked immunoadsorbent assay for protein C antigen", AM. J. HEMATOL., Vol. 22, No. 1, 1986. ABSTRACT ONLY					
	BBB	R. M. BERTINA, et al., "The use of a functional and immunologic assay for plasma protein C in the study of the heterogeneity of congenital protein C deficiency", THROB. HAEMOSTASIS, Vol. 51, No. 1, 1984. ABSTRACT ONLY					
	BBC						
	BBD						
	BBE						
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Examiner				Date Considered			

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OSMM&N File No. 2194-0042-23

Dept.: CHEMICAL

By: JDM//saf

Serial No. 09/938,728

In the matter of the Application of: Gwyn A. CUTSFORTH, et al.

For: COAGULATION ASSAY REAGENTS CONTAINING LANTHANIDES
AND A PROTEIN C ASSAY USING SUCH A LANTHANIDE-
CONTAINING REAGENT

Due Date: August 7, 2003

The following has been received in the U.S. Patent Office on the date stamped hereon

- Dep. Acct. Order Form
- PTO Cover Letter
- Amendment (19 pp.)
- Information Disclosure Statement
- PTO-1449
- Written Opinion (3 pp.)



COPY

Docket No. 2194-0042-23



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Gwyn A. CUTSFORTH, et al.

SERIAL NO: 09/938,728

GAU: 1651

FILED: August 27, 2001

EXAMINER:

FOR: COAGULATION ASSAY REAGENTS CONTAINING LANTHANIDES AND A PROTEIN C ASSAY USING SUCH A LANTHANIDE-CONTAINING REAGENT

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- ☐ Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- ☐ A check is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☒ Each item of information contained in this information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment form is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



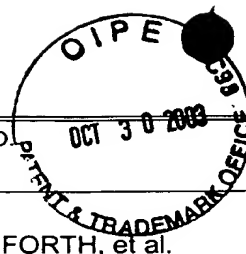
22850

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(OSMMN 05/03)

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Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 2194-0042-23		SERIAL NO. 09/938,728	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Gwyn A. CUTSFORTH, et al.			
				FILING DATE August 27, 2001		GROUP 1651	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
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FOREIGN PATENT DOCUMENTS							
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	AU						
	AV						
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AW	Written Opinion, PCT/US02/03357, International filing date: February 7, 2002, 4 pages.					
	AX						
	AY						
	AZ					<input type="checkbox"/> Additional References sheet(s) attached	
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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